Press Release

# Ipsen announces late-breaking data from first head-to-head study comparing Dysport® and Botox® in adults with upper limb spasticity

- Phase IV head-to-head, double-blind trial comparing safety and efficacy met its primary and secondary endpoints
- The DIRECTION trial results show the safety profile for Dysport® (abobotulinumtoxinA) was non-inferior to Botox® (onabotulinumtoxinA) in adult patients with upper limb spasticity
- Patients treated with Dysport in the DIRECTION trial achieved a longer duration of response than patients treated with Botox
- Data will be presented at a late-breaking session at the ISPRM congress[1]

**PARIS, FRANCE – 19 MAY 2026** – Ipsen (Euronext: IPN; ADR: IPSEY) announced today results from the only prospective, head-to-head Phase IV DIRECTION trial comparing Dysport® (abobotulinumtoxinA) to Botox® (onabotulinumtoxinA) in adults living with upper limb spasticity (ULS)[1] will be presented as a late-breaking presentation at the International Society of Physical and Rehabilitation Medicine (ISPRM) world congress in Vancouver on May 19, 2026. The trial showed that patients treated with Dysport had a non-inferior safety profile to Botox and achieved longer-lasting symptom control (based on a pre-specified 80% confidence interval)[1].

The DIRECTION trial addresses decades-long evidence gaps by delivering the first head-to-head, double-blind, comparative data between Dysport and Botox in adult spasticity. More broadly, these findings reinforce published real-world experience demonstrating that Dysport delivers durable results for patients with ULS in routine practice[2].

"Ipsen is committed to generating robust clinical evidence that supports scientific understanding and real-world practice. In spasticity, the durability of treatment response plays a critical role in patients' function, mobility and quality of life," said Sandra Silvestri, PhD, MD, Chief Medical Officer, Ipsen. "The DIRECTION data provides further support that Dysport can delay breakthrough symptoms with a well-established safety profile."

For the primary endpoint of the trial, Dysport demonstrated non-inferiority compared with Botox with a treatment-emergent adverse event rate of 20.3% vs 23.0%, respectively (adjusted difference (aboBoNT-A – onaBoNT-A) was -2.7% (80%CI: -6.2%, 0.9%)[1]. The results support the well-established safety profiles of these treatments.

In addition, the secondary efficacy endpoint was met: patients treated with Dysport experienced a longer duration of effect compared with those treated with Botox (14.2 vs 13.8 weeks, respectively; adjusted difference favoring Dysport (80%CI: 0.2, 5.9) with a pre-specified significance threshold for statistical significance (p=0.17; significance threshold, p=0.20).

Evidence of longer duration was consistent across most demographic and clinical subgroups[1] which is important as published research shows that over 80% of patients experience breakthrough symptoms between injection cycles and more than 70% of patients express a need for longer lasting treatment[3].

"Today, for the first time, we have comparative evidence that distinguishes the performance of two widely used botulinum toxin treatments in patients with spasticity," said Dr. Alberto Esquenazi, DIRECTION Principal Investigator. "These findings are based on a rigorously controlled study design and contribute meaningful data for clinicians, strengthening the evidence available for the use of botulinum toxin therapies in people with spasticity."

### About DIRECTION (NCT04936542)

DIRECTION is the first ever spasticity trial to compare Dysport® (abobotulinumtoxinA) and Botox® (onabotulinumtoxinA) directly in adults with upper limb spasticity. It is a Phase IV, randomized, double-blind, crossover trial involving 464 people living with upper limb spasticity at 72 sites across the USA, France, and Canada. Patients in the trial had an average age of 57 years, two-thirds were male, and most patients had spasticity because of a stroke.

Each participant received one treatment cycle with each toxin, administered using standardized, instrument-guided techniques to ensure fairness and comparability. The trial used a rigorous design, controlling for factors that could affect treatment outcomes including volume, dilution, dose, muscles treated, and the use of guidance. The trial was powered to detect differences in safety (primary endpoint), duration of response (a key secondary endpoint) and functional outcomes.

### About Adult Upper Limb Spasticity

Upper limb spasticity (ULS) can significantly impair function, mobility, and quality of life. Botulinum toxin type A injections are a recommended first-line treatment. Many patients express frustration with waning treatment effect before their next scheduled injection, impacting daily function and increasing caregiver burden[2].

### About Dysport

Dysport® (abobotulinumtoxinA) is an injectable form of a botulinum neurotoxin type A (BoNT-A) product, which is a substance derived from Clostridium bacteria producing BoNT-A that inhibits the effective transmission of nerve impulses and thereby reduces muscular contractions. It is supplied as a lyophilized powder. AbobotulinumtoxinA has marketing authorization in approximately 90 countries, more than 30 years of clinical experience and >18 million treatment years of patient experience.

The detailed recommendations for the use of Dysport® are described in the Summary of Product Characteristics (SmPC) for Dysport (300 units) Powder and Dysport (500 units) Powder, and the U.S. Prescribing Information (PI).

NOTE: Dysport® labels, approved indications and dilutions may vary from country to country and from the DIRECTION methodology.

### About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Our pipeline is fueled by internal and external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

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## References


1. Esquenazi A. A randomized, double-blind, head-to-head, crossover study comparing the clinical safety and efficacy of abobotulinumtoxina with onabotulinumtoxina when treating adults with upper limb spasticity. Presented at: International Society of Physical and Rehabilitation Medicine (ISPRM) World Congress; 2026 May 20; Vancouver, Canada.
2. Turner-Stokes L et al. J Rehabil Med. 2021;53:jrm00157
3. Jacinto J et al. Front Neurol. 2020;11:388.


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